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## ORIGINAL ARTICLE

# Yoghurt containing galacto-oligosaccharides, prunes and linseed reduces the severity of mild constipation in elderly subjects

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**Objective:** Constipation is a common problem in the elderly. Dietary fibre is recommended for its treatment. The aim was to examine whether yoghurt containing galacto-oligosaccharides (GOS), prunes and linseed relieve constipation in elderly subjects.

**Design:** A randomized, double-blinded, cross-over study.

**Setting:** Free-living subjects.

**Subjects:** A group of 43 elderly subjects with self-reported constipation (mean age 76 years, range 61–92 years, 32 females, 11 males).

**Interventions:** The study consisted of a 2-week baseline period and 2, 3-week dietary interventions, with a 2-week wash-out period between the interventions. During the interventions, the subjects ingested, in random order, 260 g/day of either control yoghurt or test yoghurt containing GOS (12 g/day), prunes (12 g/day) and linseed (6 g/day). The use of laxatives was controlled and only allowed after 2 days without defecation.

**Results:** Defecation frequency was 5.7 times/week during the baseline period. During the test yoghurt period, defecation frequency was higher (8.0 vs 7.1 times/week,  $P=0.011$ ), defecation was easier (on the scale 0–3, 1.3 vs 1.5,  $P=0.010$ ), and there was a tendency towards softer stools (on the scale 0–3, 2.1 vs 2.2,  $P=0.059$ ) compared with the control yoghurt period. The subjects felt that the test yoghurt relieved constipation more effectively than the control yoghurt ( $P=0.005$ ). The sum of gastrointestinal symptoms did not differ between the interventions. The use of laxatives remained constant throughout the study.

**Conclusions:** Daily intake of yoghurt containing GOS, prunes and linseed reduced the severity of constipation in elderly subjects with mild constipation.

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**Keywords:** constipation; elderly subjects; galacto-oligosaccharides; linseed; prunes

## Introduction

Constipation is a common problem among the elderly (Schaefer and Cheskin, 1998). Elderly people often have to use a wide range of medicines, some of which cause

constipation as a side effect. When people grow older, food intake decreases as their energy need is reduced, and it becomes difficult to achieve the intake of dietary fibre usually recommended for preventing constipation (Taylor, 1990).

Galacto-oligosaccharides (GOS) act as soluble fibres as they pass undigested into the colon, where they are hydrolyzed and fermented by the bacteria (Delzenne, 2003). GOS are composed of lactose and galactose units (Zaráté and López-Leiva, 1990), and are found naturally in, for example, human milk (Kunz and Rudloff, 1993; McVeagh and Miller, 1997; Kunz *et al.*, 2000). The prebiotic, bifidogenic effects of GOS or a mixture of GOS and fructo-oligosaccharides on the colonic microbiota have been shown in infants (Boehm

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*et al.*, 2002; Moro *et al.*, 2002; Knol *et al.*, 2005; Rinne *et al.*, 2005) as well as in adults (Ito *et al.*, 1990; Bouhnik *et al.*, 1997; Gopal *et al.*, 2003), and GOS are therefore considered beneficial to human health. As GOS are fermented in the colon, the bacterial mass increases and this in turn increases faecal bulk and softens stools. In a previous study, we found that in most elderly subjects a daily dose of 9 g GOS relieved constipation (Teuri and Korpela, 1998). GOS have been found to relieve constipation in Japanese studies, too (Deguchi *et al.*, 1997; Shitara, 1988). GOS are in general well-tolerated (van Dokkum *et al.*, 1999; Boehm *et al.*, 2002; Moro *et al.*, 2002). However, because of fermentation, symptoms such as abdominal bloating and flatulence may occur in sensitive subjects when large quantities of GOS are ingested (Ito *et al.*, 1990; Teuri *et al.*, 1998).

Prunes are known to soften stools and to relieve constipation (Muller-Lissner *et al.*, 2005a) and have been shown to increase faecal output in non-constipated men (Tinker *et al.*, 1991). Their efficacy in elderly subjects has been reported in a few early studies in which prunes in yoghurt (Ferrer and Boyd, 1955) or prunes with cascarn (Stern, 1966) or fibre (Hull *et al.*, 1980) have been ingested. The laxative action of prunes could be explained by its relatively high fibre and sorbitol content (Stacewicz-Sapuntzakis *et al.*, 2001). Prunes also contain phenolic compounds, mainly in the form of neochlorogenic and chlorogenic acids, which may aid the laxative action (Stacewicz-Sapuntzakis *et al.*, 2001).

Linseed is traditionally used for relieving constipation, and 50 g per day has been found to increase bowel movement in subjects with normal bowel function (Cunnane *et al.*, 1995). Linseed acts as a swelling, bulk-forming agent. Its stimulating effect on bowel movement may be partly owing to its high fibre content, especially of the soluble fibre, known as mucilage, which surrounds the linseed.

Serious constipation requires medical treatment, that is, laxatives. In mild constipation, nutritional therapy is often preferred. We therefore examined the possibility that in the elderly, a yoghurt containing 12 g GOS, 12 g prunes and 6 g linseed per day might reduce the severity of mild, self-reported constipation, compared with traditional yoghurt.

## Materials and methods

### Subjects

The study population consisted of 43 elderly subjects (>60 years, mean age 76 years, range 61–92 years, 32 female, 11 male, Table 1), who were classified as suffering from mild constipation as either (1) their bowels functioned less than five times per week without laxatives, or (2) they complained of difficulty in defecation. They suffered from various age-related chronic diseases and used a wide range of medicines. All the subjects were ambulatory and lived either on their own or in homes for the elderly. There were no dietary exclusion criteria.

**Table 1** Baseline characteristics of the study subjects. Results are expressed as number of subjects or as mean (range)

Subjects (n = 43)	
Females/males, (n)	32/11
Age, years (range)	76 (61–92)
Weight, kg (range)	78 (56–112)
BMI, kg/m <sup>2</sup> (range)	28.3 (21.0–41.8)
Fibre intake, g/day (range)	22.3 (8.9–43.9)
<i>Use of laxatives</i>	
Daily or weekly, (n)	15
Less than weekly, (n)	4
Did not use, (n)	24
<i>Period of constipation</i>	
Over 20 years, (n)	14
3–20 years, (n)	15
Less than 3 years, (n)	14
<i>Exercise such as walking outside</i>	
Every day, (n)	32
Sometimes, (n)	7
None or minimal, (n)	4

Abbreviation: BMI, body mass index.

The study protocol was accepted by the local ethics committee. Informed, written consent was obtained from all the subjects.

### Design

The study was performed as a randomized two-period cross-over study and lasted 10 weeks. First, there was a 2-week baseline period, followed by the first intervention of 3 weeks, a wash-out period of 2 weeks, and finally a second 3-week intervention period. The subjects were randomly assigned to one of the two groups, which determined the order of consumption of the two yoghurts. The subjects were randomized in blocks, and the randomization was stratified according to defecation frequency during the first week of the baseline period.

Both the test yoghurt and the control yoghurt were fermented with *Lactobacillus acidophilus* species and *Bifidobacterium lactis* (Wisby, Tønder, Denmark). GOS syrup (Elixor, Borculo Whey Products, Borculo, the Netherlands) and jam containing linseed and prunes were added to the test yoghurt: one test yoghurt portion contained 6 g GOS, 6 g prunes and 3 g linseed. Artificial prune flavour and jam containing a small quantity of prunes (0.2 g per yoghurt) were added to the control yoghurt to make its appearance and taste as similar as possible to the test yoghurt. Even so, the appearance of the yoghurts differed slightly, but the subjects were not told which was supposed to be the effective one.

Two yoghurts (each 130 g) were ingested per day, one in the morning and one in the evening, with the exception of the first 4 days of the 3-week intervention periods, when only one yoghurt was ingested per day to reduce the

gastrointestinal symptoms sometimes caused by a sudden high fibre addition to the diet. After the first 4 days of the test yoghurt period, the intake of GOS was 12 g per day, prunes 12 g per day and linseed 6 g per day. At the end of the intervention periods, the subjects were asked to return any remaining yoghurts or else the fridge was checked, so that the actual quantity of yoghurt consumed could be calculated.

Once the study began, the subjects suspended their normal use of laxatives. During the whole study, including the baseline period, laxatives were used only if there was no defecation for 2 whole days. In this case, on the third day, a laxative (Visiblin, Parke-Davis Scandinavia AB, Solna, Sweden) was taken, and if defecation did not follow, a similar laxative (Visiblin) was taken the next morning and a different laxative (Pursennid, Sandoz Pharma AG, Basel, Switzerland) in the evening. On the sixth day an enema (Microlax, Pharmacia & Upjohn AB, Stockholm, Sweden) was finally administered if defecation was not likely to be induced with milder laxatives. All laxatives were administered according to the instructions of the manufacturer. The subjects continued to consume yoghurts regularly even when they were taking laxatives.

### Questionnaires

The subjects were questioned about their intake of dietary fibre three times during the study, using a dietary fibre frequency questionnaire for the previous week (Jäkälä *et al.*, 1994). At the same time they were asked about their liquid intake in the course of an ordinary day by means of a drink questionnaire. Interviews were held at the end of the baseline period and of both intervention periods. Before the study, 7 weeks after the beginning of the study, and immediately after the study, the subjects were weighed and questioned about exercise and medication. The subjects were asked to retain their normal diets.

Throughout the study, the subjects filled in daily a questionnaire concerning faecal frequency, consistency of faeces (0 = watery, 1 = soft, 2 = normal, 3 = hard) and difficulty of defecation (0 = easy, 1 = fairly easy, 2 = rather difficult, 3 = difficult), as well as about flatulence, abdominal pain and abdominal bloating (each, 0 = no symptom, 1 = mild symptoms, 2 = moderate symptoms, 3 = severe symptoms). The use of laxatives was also registered.

Practically, all the subjects were visited twice a week to make sure that the questionnaires were filled in correctly. Immediately after the intervention periods, the subjects evaluated the effects of the yoghurt on their constipation compared with the 2 weeks before this period (0 = no effect on constipation, 1 = mild relieving effect, 2 = moderate relieving effect, 3 = considerable relieving effect).

### Statistics

The information obtained from the two baseline weeks was combined, as was the information from the last 2 weeks of

the intervention periods, by calculating the mean of all recorded values. The sum of symptoms (maximum 9 points) was calculated by adding the daily average values of abdominal pain, abdominal distension and flatulence (each from 0 to 3 points).

The test yoghurt was compared with the control yoghurt for defecation frequency, difficulty in defecation, hardness of faeces and the sum of symptoms. The conventional cross-over analysis (ANOVA) was performed to study the treatment, period and carry-over effects. The comparison of yoghurts, that is, treatment effect, is given as means with 95% confidence intervals (CI<sub>95</sub>). Individual symptoms (abdominal distension, pain and flatulence), and the effectiveness scores of the yoghurts were analysed by using the nonparametric Wilcoxon matched pairs test, and the results are presented as medians. The McNemar test was used for binary variables, and the marginal homogeneity test (extension of the McNemar test) was used for variables with more than two categories. Differences were considered significant at  $P < 0.05$ . The data were analysed using SPSS (Version 13.0).

### Results

Study compliance was good, and the intake of the study yoghurts did not differ between the two intervention periods. During the last 2 weeks of the test yoghurt period 30 subjects out of the 43 had eaten all the yoghurts given them, and the mean intake of yoghurt was 13.5 per week (range 11–14). During the control yoghurt period the mean intake of yoghurts was 13.4 per week (range 8.5–15).

The intake of dietary fibre remained constant during the intervention periods: on average 20.8 g during the test yoghurt period and 22.3 g during the control yoghurt period when dietary fibre from the yoghurt was not included. The intake of drinks (1740 vs 1710 ml) and amount of exercise ( $P = 0.774$ ) did not differ between the GOS and the control yoghurt periods.

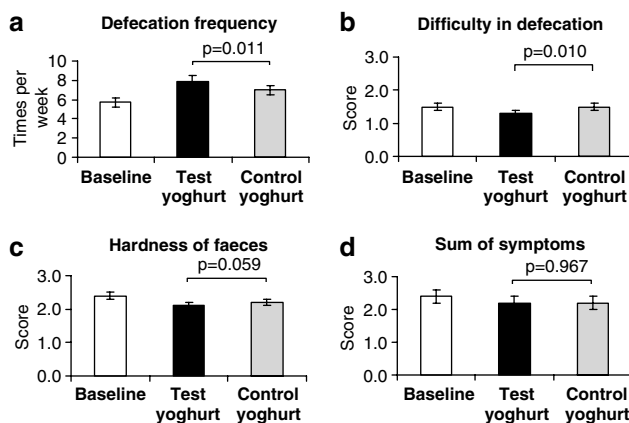
Defecation frequency was on average (mean  $\pm$  s.e.m)  $5.7 \pm 0.5$  times per week during the baseline period, and significantly higher in the test yoghurt period than in the control yoghurt period ( $8.0 \pm 0.6$  vs.  $7.1 \pm 0.5$  times per week, difference 0.9 CI<sub>95</sub> 0.2 to 1.6,  $P = 0.011$ , Figure 1a). Defecation was easier in the test yoghurt period than in the control yoghurt period (1.3 vs 1.5 points, difference  $-0.2$  CI<sub>95</sub>  $-0.3$ – $-0.05$ ,  $P = 0.010$ , Figure 1b). Stools were slightly softer in the test yoghurt period compared with the control yoghurt (2.1 vs 2.2 points, difference  $-0.1$  CI<sub>95</sub>  $-0.2$ – $0.004$ ,  $P = 0.059$ , Figure 1c). Period effects were not seen in any of the variables. A carry-over effect was seen in the difficulty of defecation, where the positive effect of test yoghurt was still present during the following control yoghurt period ( $P = 0.048$ ).

Overall gastrointestinal symptoms did not differ between the intervention periods (2.2 vs 2.2 points, difference 0.01

CI<sub>95</sub> -0.4–0.5,  $P=0.967$ , Figure 1d), but abdominal pain was less severe in the test yoghurt period than in the control yoghurt period (median scores 0.1 vs 0.3 points,  $P=0.031$ , Table 2). In five subjects, symptoms were reduced during the test yoghurt period compared with the control yoghurt period. In six subjects, the situation was the opposite, and three of them suffered from all the individual symptoms during the test yoghurt period.

The use of laxatives remained constant in the two intervention periods. Eleven of the 43 subjects needed laxatives during the intervention periods according to the standardized schedule described above. Nine subjects used laxatives during the control yoghurt period, and six during the test yoghurt period. Thirteen subjects needed laxatives during the baseline period.

Thirty-eight of the 43 subjects (88%) felt relief from the test yoghurt and 31 (72%) from the control yoghurt ( $P=0.118$ ). When the effectiveness was rated on a scale, the test yoghurt relieved constipation more effectively than the control yoghurt (median scores 2.0 vs 1.5 points,  $P=0.005$ ).



**Figure 1** Defecation frequency (times per week), difficulty in defecation (from 0=easy to 3=difficult), hardness of faeces (from 0=liquid to 3=hard), and sum of symptoms per day (includes flatulence, abdominal pain, and abdominal distension, all from 0=no symptom to 3=severe symptoms) during the three study periods (mean  $\pm$  s.e.m.,  $n=43$ ).

**Table 2** The average gastrointestinal symptom scores per day during the baseline period, the test yoghurt period and the control yoghurt period ( $n=43$ )

Symptom <sup>a</sup>	Baseline median (range)	GOS median (range)	Control median (range)	GOS vs. control P-value <sup>b</sup>
Abdominal distension	0.4 (0–2.1)	0.3 (0–2.9)	0.6 (0–2.0)	0.473
Abdominal pain	0.2 (0–1.9)	0.1 (0–2.4)	0.3 (0–2.0)	0.031
Flatulence	1.2 (0–2.4)	1.1 (0–3.0)	1.0 (0–2.5)	0.673

Abbreviation: GOS, galacto-oligosaccharides.

<sup>a</sup>Intensity of each symptom from 0 = no symptom to 3 = severe symptoms.

<sup>b</sup>Wilcoxon matched pair test.

## Discussion

In the present study, a yoghurt containing a combination of GOS, prunes and linseed was shown to be effective in the treatment of mild constipation in the elderly. In severe constipation, use of laxatives is needed. Our results show the possibility and importance of self-treatment with nutritional therapy in mild constipation. The effects of GOS, prunes and linseed were not separated in the study. However, GOS were considered to be the most effective component of the three, and GOS contributed most of the fibre content of the yoghurt. This combination was chosen because these food-stuffs contain different effective substances: GOS are soluble fibre, linseed contains fibre which is mostly insoluble but it also contains a special soluble fibre known as mucilage, and prunes contain fibre, sorbitol, xylitol and phenolic compounds, which may affect the ability of prunes to enhance gastrointestinal function.

The subjects in the present study were classified as suffering from constipation as their bowels functioned less than five times a week without laxatives or they complained of difficulty in defecation. However, the bowel function of many of the subjects was still fairly good. Therefore, the result of this study can only be applied to subjects with mild constipation.

As can be seen from both the subjective opinions of the effectiveness of the yoghurts and the objective data, the control yoghurt also seemed to be effective in relieving constipation. *L. acidophilus* and the bifidobacteria used in both yoghurts may have altered the colonic environment and made defecation easier, even in the case of the control yoghurt (Adolfsson *et al.*, 2004). The aim of our study was not to investigate the effects of different bacteria, and therefore the same ferment was used in both the control yoghurt and the test yoghurt.

Our finding of the alleviating effect of GOS, prunes and linseed on constipation accords with earlier studies on GOS (Shitara, 1988; Deguchi *et al.*, 1997; Teuri and Korpela, 1998), in which the amount of GOS consumed per day ranged from 9 to 18.5 g. Because the present yoghurt contained such a small amount of prunes and linseed, the major effect was most probably from the GOS. However, even small quantities of prunes and linseed might have had a synergistic effect with the GOS.

The intake of fibre by the elderly subjects in this study was on average low. If GOS are included in the fibre component, it can be seen that the intake of fibre in the GOS period was about one and a half times that of the control period. The importance of fibre in alleviating constipation is well known (Taylor, 1990). In addition, GOS are reported to have a bifidogenic effect (Ito *et al.*, 1990; Bouhnik *et al.*, 1997; Boehm *et al.*, 2002; Moro *et al.*, 2002; Knol *et al.*, 2005; Rinne *et al.*, 2005), and here they may have altered bowel function through an increase in bifidobacteria and a change in the colonic environment. However, there were some subjects on whom the GOS had no effect; in fact, their constipation even became more severe. The etiology of constipation is complex and it was therefore not surprising that the effects of GOS varied considerably among the subjects (Livesey, 2001; Muller-Lissner *et al.*, 2005b).

We could not reduce the use of laxatives to any significant extent by means of the test yoghurt. There were five subjects who were able to omit laxatives during the test yoghurt period, but there were also two who needed laxatives only during that period. If a subject needs laxatives, which stimulate the intestinal nerves, yoghurt with fibre may be far too mild to reduce constipation. However, it may replace some bulk laxatives whose mechanism of action is fairly similar to that of GOS.

In most subjects, the adverse gastrointestinal symptoms did not increase in the GOS yoghurt period, although GOS are highly fermentable in the colon and in some studies have been found to increase gastrointestinal symptoms (Ito *et al.*, 1990; Teuri *et al.*, 1998). Abdominal pain was on the whole reduced in the present study. However, six of the 43 subjects definitely experienced more gastrointestinal symptoms in the GOS yoghurt period than in the control yoghurt period. Indeed, gastrointestinal symptoms are common side effects of indigestible carbohydrates, which give rise to fermentation in the colon (Attar *et al.*, 1999; Suarez *et al.*, 1999; Cummings *et al.*, 2001). In our earlier constipation study (Teuri and Korpela 1998), gastrointestinal symptoms were not noticeably intensified in any of the subjects ingesting the GOS yoghurt. The GOS dose was then 9 g and no prunes or linseed were included. Perhaps increasing the amount of GOS to 12 g per day in the present study exacerbated the symptoms in the most sensitive subjects, and some subjects may not have tolerated prunes or linseed.

In conclusion, yoghurt containing GOS, linseed and prunes reduced the severity of mild constipation in the elderly subjects without significant adverse effects, though the use of laxatives could not be totally excluded.

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